Date: 11-29-06

Time: 1:30 pm EST

BLA:125197/0

Participants:

FDA: Drs. Peter Bross, Ke Liu and Boguang Zhen

Sponsor: Ms. Alison Del Vento Director of Clinical Safety, Dr. Mark Frohlich Vice President of Clinical Affairs, Mr. Matt Harmon Sr. Programmer, Ms. Helen Kim Sr. Regulatory Affairs Manager, Ms. Elizabeth Smith Vice President of Regulatory Affairs, Dr. Lianng Yuh Vice President of Biometrics

Summary of the telecon 11-29-06:

The sponsor proposed the following to be submitted to BLA:

A. Additional efficacy analyses to include:

1. Evaluation of CD54 upregulation as a continuous variable and correlation with overall survival (D9901, D9902A, Integrated)
2. Prostate cancer specific survival analysis (D9901, D9902A, Integrated)
3. Univariate subgroup analysis of 22 prognostic factors and correlation with overall survival (D9901, D9902A, Integrated)
4. Treatment effect with/without post-study chemotherapy on overall survival (D9901, D9902A, Integrated)

FDA: Submission of A1 is reasonable as long as the data were analyzed for ITT population. The analyses outlined in A2, A3, A4 were all subset analyses. The data may not provide additional information to the claim.

B. Safety update proposal to integrate the safety data from P-11 and D9902B in to the current post text tables.

FDA: Such an approach is reasonable.